equipment required because of the toxicity of the chemotherapeutic agents ..."[16]

10. Medicare began covering erythropoietin, an outpatient drug used to treat anemia in dialysis and cancer patients, almost immediately following its approval in June 1989.[17] In 1990, certain prescription immunosuppressive therapy and intravenous drugs suitable for administration in a home setting were added to Part B coverage. Coverage was again extended in 1993 to include some "oral, self-administered anti-cancer drugs."[18]

11. The Omnibus Reconciliation Act of 1989 ("OBRA 89") mandated payment of physicians based on the RBRVS. According to the GAO, the intent of this new payment system was to base physicians' payments on the relative resources used to provide a procedure, rather than on the physicians' charges.[19] This new system was to be phased-in over 5 years, beginning in 1992.[20] Eventually, the fee schedule was used "to pay physicians for more than 7,000 procedures, ranging from a routine office visit to surgical removal of a brain tumor."[21]

12. While Medicare beneficiaries had had access to supplemental insurance (known as Medigap plans) since Medicare's inception, the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") required, as of 1992, new Medigap policies to "conform to 1 of 10 standardized benefit packages, labeled Plans A through J."[22]

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16 53 Fed. Reg. 39644 (October 11, 1988).

17 Shih 1999, pp. 40-41.

18 SSB Statistical Supplement 2000, p. 44.

19 GAO Feb 1999, p. 1.

20 GAO Feb 1999, p. 28.

21 GAO Feb 1999, p. 1.

22 Fox, Peter D., Rani E. Snyder, and Thomas Rice, "Medigap Reform Legislation of 1990: A 10-Year Review," Health Care Financing Review, Spring 2003, Vol. 24, No. 3 ("Fox, *et al.* 2003"), p. 121.

II. 1992: MEDICARE PART B ADOPTS AWP

13. In November 1991, HCFA published its final rule for Medicare Part B drug reimbursement, which stated that drug reimbursement was to be based on the lesser of EAC or AWP for single-source drugs and the lesser of EAC or the median of wholesale generic prices for multi-source drugs.[23] HCFA specified that EAC "would be based on individual carrier estimates of the costs that physicians or other providers, as appropriate, actually pay for the drugs."[24] In addition, HCFA said, "For certain types of drugs, such as chemotherapy drugs, significant indirect costs such as inventory costs, waste, and spoilage could be considered by carriers if these costs were documented."[25] According to a letter from Nancy-Ann Min DeParle, HCFA administrator,

> "To implement this policy, HCFA developed a survey to get the necessary information from physicians. However, because of the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have had to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead on the average wholesale price."[26]

14. In response to a letter from one of its carriers, HCFA noted that drugs were to be reimbursed at the lowest of the national AWP, the EAC, or the actual charge, and no allowance for exceptions was made. It was not acceptable to use manufacturer prices instead of *Red Book* prices to estimate the EAC.[27]

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23 OIG, *Physicians' Costs for Chemotherapy Drugs,* A-02-91-01049, November 1992 ("OIG Nov 1992"), p. 4.

24 Congressional Research Service, Memo from Thomas Nicola (CRS) to the House Committee on Energy and Commerce Regarding Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price, August 31, 2001 ("CRS Aug 2001"), p. CRS-2, citing 56 Fed. Reg. 59525.

25 CRS Aug 2001, p. CRS-2.

26 Letter from Nancy-Ann Min DeParle (HCFA) to June Gibbs Brown (OIG) regarding OIG Draft Reports: Medicare Reimbursement of End Stage Renal Disease Drugs and Medicare Reimbursement for Albuterol, June 13, 2000 ("DeParle (HCFA) Letter to Gibbs Brown Jun 2000"), p. 1.

27 Letter from Frank Camozzi (HCFA) to Celeste Brose (Blue Shield CA), February 2, 1995, p. 1.

15. In March 1994, HCFA requested that carriers request invoice data for high volume drugs (for which expenditures exceeded $10 million in 1992) from a sample of 5 to 10 physicians.[28] The letter stated, "Section 405.509 of the regulations permits the carriers to consider additional costs when determining the estimated acquisition cost of a drug … In addition to the estimated acquisition costs, consider allowing an additional fee for the overhead of handling or dispensing drugs."[29] The purpose of Regional Carrier Letter No. 94-19, dated June 8, 1994, was "to provide national uniform instructions on how to determine the estimated acquisition cost and the average wholesale price of drugs, and to provide additional information on other aspects of drug pricing."[30] This letter stated, "In addition to the EAC, consider allowing an additional fee for the overhead of handling or dispensing drugs. For example, you might determine that an overhead allowance of 10% above the material costs would be equitable in establishing EAC."[31] On August 12, 1994, HCFA sent Regional Information Letter (RIL) 94-435, instructing a carrier to suspend data collection efforts until HCFA could obtain approval from the Office of Management and Budget ("OMB").[32]

III. 1997: BALANCED BUDGET ACT

16. The Balanced Budget Act of 1997 ("BBA 97") required adoption of the OPPS by January 1, 1999,[33] although it was not implemented until August 2000.[34]

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28 Letter from Charles Booth (Director, Office of Payment Policy, BPD) to All Associate Regional Administrators regarding "Determination of Acquisition Cost of Drugs," March 15, 1994.

29 *Ibid.*, p. 3.

30 Letter from M.J. Christenberry, Associate Regional Administrator, Division of Medicare, HCFA Regional Office VI, to All Regional Carriers, "Determination of Cost of Drugs – Action," Regional Carrier Letter No. 94-19, June 8, 1994, pp. 1-2.

31 *Ibid.*, p. 4.

32 Mentioned in letter from Darlene Debus (HCFA) to Grant Steffen (BCBS North Dakota), 1996 ("Debus (HCFA) Letter to Steffen 1996"), HHC908-1217 to 1218.

33 63 Fed. Reg. 47552 (September 8, 1998). "…implementation of the new system will have to be delayed because of year 2000 systems concerns."

34 Lieder, Tzipora R., "HCFA Launches PPS for Hospital Outpatient Services; Billing May Pose Challenge to Pharmacists," American Society of Health-System Pharmacists, August 1, 2000 ("Lieder Aug 2000") p. 1, accessible at http://www.ashp.org/news/ShowArticle.cfm?cfid=3365738&CFToken=59500826&id=593.

Medicare outpatient reimbursement underwent a substantial change as a new system with fixed, prospectively determined payments for products and services provided by hospitals in the outpatient setting was implemented. Within this system, HCFA grouped clinically similar outpatient services that used comparable levels of resources into payment groups, called Ambulatory Payment Classification ("APC") groups, similar to the Diagnosis-related Groups ("DRGs") in the inpatient prospective payment system.[35] An APC rate could include payment for the surgical procedure, medication, supplies, and operating and surgical room services.[36]

17. BBA 97 also widened the array of health plans available to Medicare beneficiaries, who had been limited to government fee-for-service or HMO plans, to include HMOs with a point of service option, preferred provider organizations, provider sponsored organizations, and private fee-for-service plans, which could all apply for certification as "Medicare+Choice" plans beginning in January 1999.[37] CMS stated, "These options should expand the choices available to Medicare beneficiaries, particularly in rural areas. Currently, 17 percent of Medicare beneficiaries are in managed care plans. It is expected that by 2005, approximately 30 percent of all Medicare beneficiaries will be enrolled in Medicare+Choice plans."[38] BBA 97 also established two high-deductible versions of Medigap plans.[39]

18. According to Nancy-Ann Min DeParle, the HCFA Administrator, in 1997, the Administration proposed to pay physicians their actual acquisition costs for drugs, but Congress did not adopt the Administration's proposal. "Instead, the Balanced

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35 Kwong, Melsen and Rita Shane, "Medicare Outpatient Prospective Pricing System—A Pharmacy Perspective," Cedars-Sinai Medical Center, CA, American Society of Health-System Pharmacists, October 5, 2000 ("Kwong and Shane Oct 2000"), p. 1, available at http://www.ashp.org/practicemanager/mopps1.cfm.

36 Kwong and Shane Oct 2000, p. 2.

37 Center for Medicare and Medicaid Services, "New Health Options Available Under Medicare+Choice," June 18, 1998 ("New Health Options"), pp. 1-2, available at http://new.cms.hhs.gov/apps/media/press/release.asp?Counter=71.

38 New Health Options, p. 2.

39 Fox, *et al.* 2003, p. 125.

Budget Act ["BBA"] reduced Medicare payments for covered drugs from 100 percent to 95 percent of the average wholesale price."[40] The regulations specified that single-source, brand-name drugs were to be reimbursed at 95 percent of AWP and that multi-source drugs (with two or more competing brands or generic equivalents) were to be reimbursed at 95 percent of the lower of: "(a) the median AWP for all generic forms of the drug or (b) the lowest brand name product AWP."[41] However, carriers had substantial discretion in implementing the methodology, which resulted in a "wide variation" in payment rates. Carriers differed as to whether they chose to "blend" or select the lowest brand name AWP, their source of AWPs, how frequently they updated AWPs, and other factors.[42] The variation in reimbursement rates across carriers for the same drug could be as much as 20 percent.[43]

19. In November 1999, out of concern that the OPPS payment rates, which were based on 1996 expenditures, might not reflect the costs of newer, more expensive drugs, Congress enacted a modification to the BBA 97 that established a list of "transitional pass-through" drugs.[44] These transitional pass-through drugs, which were to remain on the pass-through list for at least two but no more than three years, would be reimbursed separately from APC groups. After the transitional

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40 DeParle (HCFA) Letter to Gibbs Brown Jun 2000, p. 1.

41 MedPAC, Report to the Congress: Variation and Innovation in Medicare, Jun 2003 ("MedPAC Jun 2003"), pp. 153-154. According to HCFA, "Section 4556 of BBA established payment for drugs not paid on a cost or prospective payment basis at the lower of the actual billed amount or 95 percent of the AWP, effective January 1, 1998." (See HCFA, "Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999," 63 Fed. Reg. 58814 (November 2, 1998) at 58849.)

42 "The OIG found wide variation in prices paid by local carriers for covered drugs even though all payments were based on the same formula. Much of the difficulty stems from differences in how physician-administered drugs are coded by Medicare as well as many private payers ... While some HCPCS codes correspond to only one NDC, others can represent as many as ten ... Carriers had to choose the AWP from a single NDC code or compute an AWP from several corresponding NDC codes. Each carrier could make a different decision. Carriers also differed in frequency of updating AWPs." (MedPAC Jun 2003, p. 154.) See also OIG, *Excessive Medicare Payments for Prescription Drugs*, OEI-03-97-00290, December 1997 ("OIG Dec 1997"), p. 9.

43 "For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP ... For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State." (OIG Dec 1997, p. 9.)

44 Kwong and Shane Oct 2000, pp. 2-3, and Lieder Aug 2000, p. 1.

period, payments for the APCs would be updated to include the cost for these drugs.[45] Pass-through payments for these drugs were generally reimbursed at the lesser of the billed charge or 95 percent of AWP.[46]

20. In 1999, 6,267,379 (17.2 percent of total) community dwelling Medicare beneficiaries were enrolled in Medicare Risk HMOs, up from 1,068,187 (3.3 percent of total) beneficiaries enrolled in such plans in 1991. Over the same period, the number of community dwelling Medicare beneficiaries enrolled in Fee-for-Service ("FFS") plans with no supplemental insurance decreased from 4,229,998 (13.1 percent of total) to 3,916,927 (10.8 percent of total).[47]

21. On September 5, 2000, Senator John Ashcroft introduced a bill, "Cancer Care Preservation Act." Senator Ashcroft expressed concern about the proposed Medicare cuts in outpatient drug reimbursement through use of revised AWPs and discussed the awareness of the cancer community, the GAO and the HCFA of the inadequacy of reimbursement for professional services.[48] The Senator said that the planned cuts in Medicare reimbursement would force physicians to send patients back to the hospital for treatment, but his bill would place restrictions on HCFA's ability to implement any changes to payment for outpatient cancer treatment, unless agreed to by the GAO, MedPAC, and members of the cancer community, and also would require the GAO to conduct a nationwide analysis to determine the appropriate payment rates for cancer services administered to Medicare beneficiaries.[49]

22. On September 8, 2000, HHS issued a program memorandum that provided revised AWPs to be used for 32 drugs, but specifically excluded their application

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45 Lieder Aug 2000, p. 1.

46 Balanced Budget Act of 1997, H.R. Rep. No. 217 105th Congress, 1st Session, p. 798.

47 Murray, Lauren A., and Franklin J. Eppig, "Insurance Trends for the Medicare Population, 1991-1999," *Health Care Financing Review*, Spring 2002, Vol. 23, No. 3, pp. 9-15, at p. 10.

48 Statements on Introduced Bills and Joint Resolutions, By Mr. Ashcroft (for himself, Mr. Hagel, and Mr. Abraham), Statement regarding S. 3003, the Cancer Care Preservation Act, Congressional Record – Senate, September 5, 2000, S8022-8023 ("Ashcroft Statement Sep 2000), p. S8022.

49 Ashcroft Statement Sep 2000, pp. S8022-23.

to 17 drugs. HCFA authorized Medicare carriers to use these revised prices, which had been obtained in the DOJ and National Association of Medicaid Fraud Control Units ("NAMFCU") investigations of providers' drug acquisition costs.[50]

23. In a letter to Members of Congress, Nancy-Ann Min DeParle, the HCFA Administrator, stated, "This policy [reducing reimbursement to 95 percent of AWP under BBA 97] captures only a small fraction of the excessive Medicare payment amounts, as average wholesale price data do not reflect actual costs for many Medicare-covered drugs. Therefore, the Administration has proposed to pay 83 percent of the average wholesale price."[51]

24. In November 2000, HCFA retracted their authorization regarding use of these new AWPs, due to impending congressional actions.[52] Shortly after this, Congress passed section 429 of the Benefits Improvement and Protection Act ("BIPA"), which mandated that the GAO study reimbursements for Part B drugs and for their administration and provide recommendations regarding modifications to the reimbursement system. The legislation also imposed a moratorium on any direct or indirect decrease of drug reimbursement after January 1, 2001.[53] HCFA conveyed to its carriers that they believed that the moratorium applied to changing the discount to AWP at which it would reimburse, but did not apply to any change in payment allowances resulting from marketplace factors such as entry of a generic version of a Part B drug.[54]

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50 DHHS and HCFA, Program Memorandum – Intermediaries/Carriers, *An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Transmittal AB-00-86, September 8, 2000 ("Transmittal AB-00-86"), p. 2. The excluded drugs were chemotherapy agents and blood clotting factors.

51 Letter to Members of Congress from Nancy-Ann Min DeParle, HCFA Administrator, reproduced in *Medicare Part B Resource: Focused Information for Medicare Part B Providers in Maine, Massachusetts, New Hampshire, and Vermont*, October/November 2000, published by the National Heritage Insurance Company of Hingham, Massachusetts, pp. 17-18.

52 DHHS and CMS, Program Memorandum, Transmittal AB-00-115, November 17, 2000 ("Transmittal AB-00-115"), p. 1.

53 DHHS and CMS, Program Memorandum, Transmittal AB-01-66, May 3, 2001.

54 CRS Aug 2001, p. CRS-7.

25. In order to "correct identified differences amongst its local carriers," CMS established the Single Drug Pricer ("SDP") program, effective January 1, 2003.[55] Under this new program, CMS establishes prices centrally[56] and distributes the SDP list to carriers every quarter.[57] Drugs subject to the SDP include all Medicare-covered drugs for which the payment allowance is based on AWP, except for drugs billed to DME carriers and hospital outpatient drugs billed to fiscal intermediaries.[58]

IV. 2003: MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT

26. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Medicare outpatient prescription drug benefit, effective in 2006; changed the rates at which Medicare Part B drugs were reimbursement for 2004; and introduced a new reimbursement benchmark, the Average Sales Price ("ASP"), for drugs dispensed under Medicare Part B after January 1, 2005. The MMA also authorized the CMS to study physician practice expenses and revise payments for drug administration. For 2004, most Part B drugs were reimbursed at 85 percent of the AWP in effect on April 1, 2003, while blood clotting factors, drugs that were not available for Medicare payment on April 1, 2003, vaccines, ESRD drugs, and infusion drugs used with DME were reimbursed at 95 percent of AWP.[59]

27. Section 303(d) of the MMA "establishes a program for the acquisition of and payment for competitively biddable Part B covered drugs and biologicals

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55 DHHS and CMS, Program Memorandum, Transmittal AB-02-174, December 3, 2002 ("Transmittal AB-02-174"), Attachment.

56 CMS chose Palmetto GBA to determine AWPs for the program. See MedPAC Jun 2003, p. 160.

57 Transmittal AB-02-174, p. 2.

58 "Standardizing Prices for Medicare Covered Drugs," Palmetto GBA, accessed at http://www.palmettogba.com/palmetto/providers.nsf/PrintFrame?OpenFrameSet&Frame=PrintBottom&Src=/palmetto/providers.nsf/PrintableDocs/85256A46005D491A85256C9300493BD4?OpenDocument.

59 "Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004, Interim final rule with comment period," 69 Fed. Reg. 1084 (January 7, 2004). DME infusion drugs were reimbursed at 95 percent of the AWP in effect on October 1, 2003. (See 69 Fed. Reg. 1086.)

furnished on or after January 1, 2006."[60] This section provided physicians with two options for acquiring the drugs administered to Medicare patients: they could obtain drugs from an entity selected to participate in the Competitive Acquisition Program or they could continue to purchase drugs and bill Medicare under the ASP drug payment methodology.[61]

28. "Effective January 2005, Medicare pays for the majority of Part B covered drugs using a drug payment methodology based on the ASP. In accordance with section 1847A of the Act, manufacturers submit to us [CMS] the ASP data for their products. These data include the manufacturer's total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Act). The Medicare payment rate is based on 106 percent of the ASP (or for single source drugs, 106 percent of wholesale acquisition cost (WAC), if lower), less applicable deductible and coinsurance."[62]

29. The MMA also created two methods for reimbursing for prescription drugs under OPPS. First, charges for low-cost drugs (defined as drugs with daily median costs below $50) were bundled into their associated APC groups.[63]

> "In 2004, the reimbursement rate [for higher cost drugs] was 88% of the average wholesale price (AWP) for single-source medications, 68% of AWP for multi-source medications, and 46% of AWP for generic medications. In 2005, the rate will decrease to 83% of AWP for single-

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60 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B, Final rule with comment," 70 Fed. Reg. 70116 (November 21, 2005), at 70 Fed. Reg. 70236.

61 70 Fed. Reg. 70236 (November 21, 2005).

62 "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," Interim final rule with comment period," 70 Fed. Reg. 39023 (July 6, 2005).

63 American Society of Health-System Pharmacists, *Pharmaceutical Reimbursement: Keeping Up With Changing Times*, December 5, 2004, p. 6.

source medications and remain the same for multi-source and generic medications. In 2006, the rate will be 106% of the average sales price (ASP) or average acquisition cost."[64]

64 *Ibid.*

APPENDIX C: INFORMATION ON PHARMACUETICAL PRICING FROM NON-GOVERNMENT SOURCES

1. This appendix focuses on non-government documents regarding the acquisition cost and reimbursement of pharmaceuticals. Many of the references indicate that the private sector has been exposed to and acted upon information generated in the public sector. For instance, *Drug Topics* refers to Medicaid programs as the "trend-setters" for third party prescription plans[1] and the "leaders" in a game of "follow the leader."[2] A 1994 *Health Care Financing Review* article commented that Medicaid policy was especially significant, because private payors "often mimic their own States' Medicaid payment methods for prescription drugs."[3] In addition, private insurance companies acted as carriers, or local administrators of the Medicare and Medicaid programs, and received regular data and guidance from the federal government concerning reimbursement levels and actual acquisition costs.[4] Further, deponents have testified that their companies used Medicare reimbursement levels as a reimbursement benchmark.[5]

2. Since at least the late 1980s, there have been numerous references to government studies about prescription drug prices in newspaper and journal articles. These articles cite studies and reports from the OIG,[6] the Congressional Budget Office

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1 Robinson, Bill, "Medicaid at 20: Still Awkward and Troubled," *Drug Topics*, April 21, 1986, p. 36.

2 Ehrlich, Frederick J, "Learning To Live With Third Party," *Drug Topics*, February 17, 1986, p. 38.

3 Lamphere-Thorpe, Jo Ann, William P. Johnston, Kerry E. Kilpatrick, and G. Joseph Norwood, "Who Cares What it Costs to Dispense a Medicaid Prescription?," *Health Care Financing Review*, March 22, 1994, p. 9.

4 OIG, *Changes to the Medicaid Prescription Drug Program Could Save Millions*, A-06-40216, September 1984, p. 3.

5 See, for example, Beaderstadt (John Deere) Deposition, pp.17-19 and Deposition of Michael T. Mulrey, Manager of Provider Reimbursement in the Actuarial Department, Blue Cross Blue Shield of Massachusetts ("BCBS-MA"), January 5, 2006, pp. 61-63.

6 Alpert, Bill, "Hooked on Drugs: Why do Insurers Pay Such Outrageous Prices for Pharmaceuticals?" *Barron's*, June 10, 1996 ("Alpert 1996"), p. 15.

("CBO"),[7] the New York State Consumer Protection Board,[8] and the Senate Special Committee on Aging.[9] Furthermore, these articles were published in widely-read publications such as the *Los Angeles Times, Newsday,* and *The Washington Post.* There was also extensive coverage of Congressional Hearings in 2001 and 2002 and of the debate surrounding the Medicare Modernization Act.

I. 1980s

3. An article published in the July 5, 1987, *Lexington Herald-Leader* (KY) quoted the director of regulatory affairs for Rugby Laboratories as saying, "The (Average Wholesale Price) is a joke" and quoted a top Pennsylvania Medicaid official as saying that AWP "just doesn't mean anything. It has no connection to what pharmacists really purchase the drug for."[10] This article also discussed an audit by the OIG conducted in 1985, stating "It [the audit] concluded that Average Wholesale Prices were, on the average, 16 percent too high."[11] Later in 1987, *Drug Topics* reported that HCFA had "made clear its position that AWP is generally not a good guidepost in determining pharmacists' drug costs."[12]

4. In 1989, *Newsday* noted that "insurers say the average wholesale price isn't the price they pay for drugs. Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price."[13] In the same year, the *Arkansas Democrat-Gazette* published an interview with Bill McCutcheon, a

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7 Dillon, Michael J., "Drug Pricing: One Size Fits None," *Journal of Commerce*, August 3, 1994, p. 6A; Enthoven, Alain, "Discounts: A Healthy Dose of Competition," *The Washington Post*, August 11, 1999 ("Enthoven 1999"), p. A19.

8 Unger, Michael, "Study Finds Drug Prices Vary Widely: Consumer Board Sees Spread of up to 700%," *Newsday*, August 28, 1990 ("Unger 1990"), p. 41.

9 Rosenblatt, Robert A., "Catastrophic Care Would Pay More for Drugs than VA, Study Finds," *Los Angeles Times*, July 16, 1989, Part 1, p. 16.

10 Miller, John Winn, "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars," Lexington Herald-Leader, July 5, 1987 ("Miller 1987"), p. A1.

11 Referring to OIG, *OIG Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program*, October 3, 1989.

12 Robinson, Bill, "New Medicaid Drug Rules: Reform or Retreat," *Drug Topics*, September 7, 1987, p. 54.

13 Sanger, Elizabeth, "No Rx for Plans; Drug Plans Draw Pharmacists' Ire," *Newsday* (New York), February 24, 1989, p. 47.

HCFA deputy regional administrator, in which he said that even the publishers of AWP openly admit that AWP "'doesn't represent the actual cost' to pharmacies 'by any stretch of the imagination.'"[14] This article also reported that HCFA had "recently ruled that the average wholesale price [was] no longer an acceptable reimbursement standard." Another 1989 *Arkansas-Democrat Gazette* article looked at prices for Zantac and found that the AWP was $63, that pharmacies could purchase it at $55, hospitals could purchase it at $53, and the Veterans Administration could purchase it for $41.[15]

5. In 1989 the *Washington Post* reported that "[t]he generally accepted practice in the industry has been to use 'the average wholesale price' – something akin to the 'blue book' value of an automobile – as a way to measure the cost of the drug."[16] This article discussed a study commissioned by Mack Trucks that found pharmacies could buy brand name drugs for AWP minus 15 percent and generic drugs for AWP minus 50 percent.

II. 1990s

6. Between 1990 and 1993, many newspaper and journal articles discussed pharmaceutical discounts in connection with the Congressional hearings on the Medicaid best-price legislation. Publications such as *Drug Topics*,[17] the *Los Angeles Times*,[18] *The New York Times*,[19] and *The Seattle Times*[20] published articles discussing the varying levels of discounts and rebates received by

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14 "Pharmacists Face Big Losses Under Proposal, Official Says," *Arkansas Democrat-Gazette*, March 23, 1989.

15 Henson, Maria, "Pryor Going after Lower Drug Prices," *Arkansas Democrat-Gazette*, July 17, 1989.

16 Sun, Lena H., "Prescription Drug Plans Face Threat; Pharmacy Chains Dropping Programs," *The Washington Post*, April 14, 1989, p. A1.

17 Conlan, Michael F., "Now Come Some Serious Medicaid Cuts," *Drug Topics*, September 17, 1990, p. 45.

18 Reynolds, Maura, "Medicaid Savings," *Los Angeles Times*, November 20, 1990, Part A ("Reynolds 1990"), p. 5.

19 Freudenheim, Milt, "Business and Health; Medicaid Fight by Drug Makers," *The New York Times*, July 31, 1990, Section D, p. 2.

20 King, Warren, "Drug Companies Hit Over Price Boosts—Hospitals, Other Health Organizations Report Increases of 20 Percent or More," *The Seattle Times*, February 17, 1991, p. A1.

different classes of trade and the federal government. These discounts ranged from 10 to 70 percent according to the *Los Angeles Times*;[21] while the *Arkansas Democrat-Gazette* reported that discounts could range from 25 to 60 percent.[22] The *Los Angeles Times* quoted Professor Stephen Schondelmeyer as saying, "Many hospitals get products at 40 to 60% less than what the retail pharmacy pays."[23]

7. An article published in *Trustee* in 1991 discussed the impact of the Medicaid Best Price legislation on the prices charged to hospital buying groups and mentioned two instances in which hospital purchase prices have skyrocketed: for Yale-New Haven Medical Center, the price of Coumadin went from $2.10 to $42.12; the price of warfarin at the University of Wisconsin Hospital and Clinic was raised from $1.80 to $36.70.[24]

8. In 1993, publications such as the *Washington Post* began to cover *In re: Brand Name Prescription Drug Litigation*, in which pharmacies complained about pharmaceutical price differentials across different classes of trade.[25] In October 1993, the *Los Angeles Times* reported retail drugstores as saying they paid up to 1,200 percent higher prices for drugs than did health maintenance organizations ("HMOs"), and mail-order pharmacies.[26] The *Chicago Sun-Times* reported that retail pharmacists paid drug prices that were up to 1,245 percent higher than those paid by other classes of trade.[27]

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21 Reynolds 1990, p. 5.

22 "Drug Price Surge Hits VA Hospitals," *Arkansas Democrat-Gazette*, February 24, 1991.

23 "Drug Firms Start Holding Line on Prices," *Los Angeles Times*, January 12, 1992, Business, Part D, p. 11.

24 Chaconas, Judy, "Providers Offer Prescription for Medicaid Drug-Pricing Law," Trustee, December 1991, p. 19.

25 Mathews, Jay, "Drugstores Accuse Firms of Fixing Drug Prices," *The Washington Post*, October 15, 1993 ("Mathews 1993").

26 Gellene, Denise, "Suit Accuses 7 Drug Makers of Price-Fixing," *Los Angeles Times*, October 15, 1993, Part D, p. 1.

27 Mathews, Jay, "Chains Accuse Drug Firms of Price-Fixing," *Chicago-Sun Times*, October 15, 1993, p. 6.

9. In 1996, *The New York Times* reported that HMOs received discounts and rebates from drug manufacturers by "contending they can push tens of thousands of patients toward one or another brand, or often a low-priced generic copy, at the expense of similar drugs."[28] The *Chicago Tribune* reported that managed-care organizations, mail-order pharmacies, hospitals, and nursing homes could purchase drugs at prices 40 to 95 percent lower than the prices available to retail pharmacies.[29] Also in 1996, the *Washington Post* reported that AWP is a "price that is used as a baseline to negotiate prices and reimbursement rates."[30]

10. In 1996, staff at *Barron's* performed an analysis of pricing for the "top 20 Medicare drugs (which account for about 75% of the program's drug spending), as well as for various intravenous solutions."[31] They followed a methodology similar to that employed in the OIG studies discussed in Exhibit C, comparing AWPs listed in the *Red Book* and the *Blue Book* with "current quotes or price lists from several leading wholesaler[s] specializing in sales to doctors, home health firms, nursing homes and hospitals."[32] They found that "for generic drugs, nearly every manufacturer's price was 60%-85% below the published average wholesale price" and that for intravenous nutritionals and solutions, "[c]atalog wholesale prices … are, on average, 80%-93% below those companies' AWPs," concluding, "If most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means 'Ain't What's Paid?'."[33]

11. A January 1997 article in *The Washington Post* said AWP is "not … the price that's really charged [to] most customers."[34] Also in January 1997, an article in

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28 Freudenheim, Milt, "The New Drug-Price Squeeze; H.M.O.'s are Fighting Back in the Battle over Costs," *The New York Times*, March 13, 1996, Section D, p. 1.

29 Hutchcraft, Chuck, "Drug Suit Prescription has Pharmacists Queasy; Some Fear Settlement Won't Cure Sales Ills," *The Chicago Tribune*, February 19, 1996, Business, p. 1.

30 Day, Kathleen, "A Bitter Pill to Swallow; Small Pharmacies a Dying Breed as Profit Margins Shrink; Druggists' Dilemma," *The Washington Post*, February 26, 1996, p. F01.

31 Alpert 1996, p. 15. They noted that the OIG was also investigating pricing for these drugs.

32 Alpert 1996, p. 15.

33 Alpert 1996, p. 15.

34 Rich, Spencer, "Battling the High Prices Medicare Pays for Drugs," *The Washington Post*, January 2, 1997, Section A, p. A15.

The Pink Sheet stated, "Pharmacists would receive Medicare reimbursement at the actual or estimated cost of outpatient drugs rather than average wholesale price under language expected to be included in President Clinton's budget for fiscal year 1998."[35] A week later, *The Pink Sheet* reported on an OIG audit of state Medicaid payment rates, which found that AWP overstated pharmacy acquisition costs by 18.3 percent for brand-name drugs and by 42.4 percent for generic drugs.[36]

12. In a 1997 radio address, President Clinton referred to AWP as "the so-called sticker price" for drugs and said, "Few doctors, however, actually pay the full sticker price."[37]

13. One article published in *Cancer Economics* in March 1997 discussed the Administration's budget proposal to reduce reimbursement to 80 percent of physicians' actual acquisition cost, stating "If adopted, the proposal would eliminate a major source of revenue for oncologists and, according to many observers, may lead physicians to administer chemotherapy in the hospitals, thereby actually increasing healthcare costs."[38] Another article in the same issue quoted the chief medical officer at United HealthCare Corp. as saying in a speech to the National Cancer Centers Network, "The markups for chemotherapy medicines are getting to be so high that the public is beginning to react. You are losing credibility from that. What you will see happening in my company and, I suspect, others, is that you will no longer be getting reimbursed at (Average

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35 "Medicare Coverage of Outpatient Dialysis, Transplant and Cancer Drugs Would Be Tied to Actual Cost Rather than AWP Under Language Expected in Clinton '98 Budget," *The Pink Sheet*, January 6, 1997, p. 5.

36 "AWP Overstates Actual Pharmacy Invoice Cost for Brand Name Drugs by Average of 18.3% Nationwide, HHS IG Concludes; Generic AWP Overstates Cost by 42.5%," *The Pink Sheet*, January 13, 1997, p. 7.

37 "Clinton Wants Stricter Curbs on Doctor Charges for Drugs," *Chicago Tribune*, December 14, 1997, p. 5.

38 "Administration Proposes Cut Of Markup On Outpatient Drugs," *Cancer Economics*, a Supplement to the *Cancer Letter*, March 1997, p. 1.

Wholesale Price). You will be getting reimbursed at catalogue prices."[39] He was also quoted as saying, "Employers are already bringing this up to me. 'What are you doing about oncologists who are making too much money on drugs?'"[40]

III. 2000 TO THE PRESENT

14. A 2000 *New York Times* article quotes Patricia Wilson, a pharmaceutical consultant, as saying "[t]hey [AWPs] are not an average, not wholesale and not a price, other than what employers pay."[41] A June 2000 *Drug Topics* article noted, "Shaughnessy [Product Manager for *Red Book*] likened AWP to a sticker price on a new car. 'No one actually really pays that price,' he said. 'There are various market conditions that go into the price of a product.'"[42] In May 2000, an article in *USA Today* discussed the letters that House Commerce Committee Chairman Tom Bliley sent to "at least seven drugmakers [asking them to] explain how they set prices for certain products covered by Medicare and Medicaid."[43] The article mentioned the "new drug price-reporting effort," saying, "Under the new effort … [t]he difference in price could be stunning. In Florida, for example, the reimbursement for a liter of dextrose dropped from $13 to $3.88, and for Ativan, an injectable sedative, the reimbursement went from about $93 to $48."

15. A second 2000 *New York Times* article quoted U.S. Secretary of Health and Human Services, Donna Shalala, as saying that Medicare was paying "far more than doctors pay for many of the medicines."[44] According to this article, a 1997 HHS study found that "Medicare payments for 22 drugs, including many cancer drugs, exceeded the actual wholesale prices by 29 percent, or $447 million, in

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39 "Insurers are Eliminating Markup On Cancer Drugs, Official Says," *Cancer Economics*, a Supplement to the *Cancer Letter*, March 1997, p. 3.

40 *Ibid.*, p. 1.

41 Freudenheim, Milt, "New Questions on Drug Plans as Costs Soar," *The New York Times*, May 7, 2000, Section 1, p. 1.

42 Conlan, Michael F, "AWP under Fire Again at Federal and State Levels," *Drug Topics*, June 5, 2000, p. 48.

43 Appleby, Julie, "House Committee Asks Drug Firms To Justify Pricing Policy," *USA Today*, May 10, 2000, p. 1B.

44 Pear, Robert, "Administration Plans Cuts in Some Drug Payments," *The New York Times*, Section 1, August 6, 2000, p. 12.

1996. For 8 of the 22 drugs, it said, Medicare paid more than twice the actual wholesale price." *The Wall Street Journal* reported on an "18-month investigation into drug-industry pricing practices by the House Commerce Committee," stating "[f]or example, according to a wholesale catalog, health-care providers in June could buy 15 units of Pharmacia Corp.'s cancer drug Bleomycin for about $140. But Medicare reimbursements were set at 95% of the announced price of $309.98. That meant doctors buying Bleomycin could make about $154 on each purchase."[45] The article also stated, "Drug companies argue that the government has long known that announced prices for these drugs ... represented a 'sticker price,' not the actual cost to doctors. After relying on AWP to set Medicare and Medicaid reimbursements for years, the government can't honestly claim to have been bilked, the companies say."

16. In late 2000, *Pharmaceutical Executive* reported that the House Commerce Committee had found that TAP and other pharmaceutical companies had been publishing AWPs that were much higher than acquisition costs.[46]

17. In 2001, an article in *Formulary* stated that AWP "does not represent the true transaction cost."[47] Numerous articles describing the Congressional hearings on Medicare reimbursement in September 2001 were published. *USA Today* also reported Deputy Inspector General Grob's written testimony and quoted him as saying, "Until the system is changed, Medicare ... will continue to pay excessive amounts for prescription drugs."[48] *The Boston Globe* reported on the upcoming hearing, stating, "Authorities in Massachusetts and across the nation are not waiting for Congress to act. Government sources said prosecutors at the US

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45 Cloud, David S. and Laurie McGinley, "How Drug Makers Influence Medicare Reimbursements to Doctors," *The Wall Street Journal*, September 27, 2000.

46 Brichacek, Andra, "Medicare Manipulation: Government Looks The Other Way As Physicians Line Their Pockets With Taxpayer Money," *Pharmaceutical Executive*, November 1, 2000, p. 170.

47 Malone, Daniel C., Sean D. Sullivan, David L. Veenstra, Edward P. Armstrong and Amy J. Grizzle, "Determining Unit Cost Values for Health Care Resources in Pharmacoeconomic Studies," *Formulary,* April 1, 2001, p. 294.

48 Appleby, Julie, "Feds To Ask Today For Medicare Drug Change," *USA Today*, September 21, 2001 (quotation shortened in original).

attorney's office in Boston and the Massachusetts attorney general's office are investigating whether at least 20 pharmaceutical companies committed fraud by manipulating the prices of drugs reimbursed through Medicare and Medicaid."[49] *The Seattle Times*' report on the hearings discussed the excessive Medicare reimbursement, but also quoted Larry Norton, president of the American Society of Clinical Oncology ("ASCO"), as saying, "The cost of supplies, equipment, and nurse time for a chemotherapy infusion significantly exceeds the Medicare payment amount. Medicare pays less than one-fourth of the total costs."[50]

18. On December 20, 2001, *PR Newswire* covered the filing of a lawsuit by the Prescription Access Litigation ("PAL") project against "28 U.S. drug companies for manipulating the 'average wholesale price' of drugs covered by Medicare."[51] *Business Wire* covered the filing of a suit by Steve Berman, acting as "special assistant attorney general for the state of Nevada," alleging that "drug companies engaged in deceptive trade practices by manipulating or misstating the average wholesale price..."[52] In February 2002, *American Health Line* covered the filing of a suit by the attorney general of Montana alleging that 18 drug companies "illegally misstated the average wholesale prices of their medications...."[53]

19. An article in the January 21, 2002, issue of *Drug Store News* discussed both a study by the OIG that "... concluded that retail pharmacies pay an average of nearly 22 percent below average wholesale prices for the drugs they obtain" and a study performed by the Center for Pharmacoeconomic Studies at the University of

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49 Dembner, Alice, "Medicare Waste Raises Cost of Drugs by $1B: Congress to Hear Report on Overpayment Excess," *The Boston Globe*, September 21, 2001, p. A2.

50 "Medicare Drug Pricing Faces Congressional Fix; Many HMOS Trimming Their Program Coverage," *The Seattle Times*, September 22, 2001, p. A10.

51 "Consumer Groups Charge Industry-Wide Price Manipulation—Over $800 Million in Illegal Profits from Medicare & Medicare Patients; Federal Lawsuit Charges 28 Drug Companies with RICO, State and Federal Anti-Trust, and Consumer Protection Violations," *PR Newswire*, Boston, December 20, 2001.

52 "Hagens Berman Assists Nevada in Charging Drug Companies with Fraudulent Pricing Schemes," *Business Wire*, January 25, 2002.

53 "Montana: Accuses 18 Drug Makers of Price Manipulation," *American Health Line*, February 26, 2002.

Texas that disputed the OIG's findings.[54] An article in *The Metropolitan Corporate Counsel* in March 2002 stated, "Indeed, for several decades, the federal government has been aware that the Medicare and Medicaid programs have been reimbursing for certain drugs at prices higher than their actual acquisition cost to private parties, physicians and others."[55]

20. A 2002 article in the *St. Petersburg Times* said that oncologists generally receive large discounts off AWP, so that Medicare reimbursement rates at or close to 100 percent of AWP exceeded the cost of the drug to the physician.[56] In 2002, Asela Cuervo, general counsel for the American Association for Homecare, was quoted as saying "[i]t's no surprise to anybody that the AWP contains a large spread from the actual acquisition price."[57] The article also said, "Even its defenders agree that AWP is 'wholesale' in name only, and that, for many drugs, it sets reimbursement levels far above the prices that providers typically pay."

21. The February 13, 2003, edition of *The New York Times* carried an article on lawsuits that New York State Attorney General Spitzer intended to file against two major pharmaceutical companies and mentioned that six other states had filed similar suits, including California and Texas.[58] The article gave information on markups for Taxotere (19 percent), Camptosar (19 percent), Kytril (34 percent), and Anzemet (79 percent). These filings were also discussed in a number of newspaper articles published on February 14, 2003, including the *Philadelphia Inquirer* and *Newsday*.[59]

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54 Frederick, James, "Federal Drug Price Data Flawed, Charges University Of Texas Study," *Drug Store News*, Vol. 24, No. 1, January 21, 2002, p. 10.

55 Sanzo, Kathleen M. and Stephen Paul Mahinka, "Pharmaceutical Pricing: System Changes and Global Effects, *The Metropolitan Corporate Counsel*, March 2002, p. 24.

56 "Medicare Markup For Drugs: 10,000%," *St. Petersburg Times* (Florida), July 14, 2002, p. 1A.

57 Gray, Tom, "Construction Ahead," *HomeCare*, October 2002, p. 10.

58 Abelson, Reed, and Jonathan D. Glater, "New York Will Sue 2 Big Drug Makers on Doctor Discount," *The New York Times*, Sections A, February 13, 2003, p. 1.

59 Pugh, Tony, "N.Y. sues Glaxo and Pharmacia over Drug Prices," *Philadelphia Inquirer*, Business, February 14, 2003; Marshall, Randi F., "Spitzer Sues Drug Makers," *Newsday*, February 14, 2003, p. A08.

22. A Health Policy Report entitled, "Medicare and Drug Pricing" was published in the April 17, 2003, issue of the New England Journal of Medicine. According to the article, "The challenge facing policymakers is to strike a balance between the overpayments for drugs and the underpayments for practice expenses that will satisfy the disparate stakeholders."[60] The report also pointed out that the first administrative action by CMS after October 2002 testimony by the Administrator of CMS was the announcement of a "'single drug pricer' to eliminate the variation in prices paid by its local carriers according to how they apply the current payment method."[61]

23. In August 2003, *The New York Times* quoted "the administration" as saying, "Doctors typically pay 66 percent to 87 percent of the average wholesale price."[62] An August 2003 *Saint Paul Pioneer Press* article quoted Warrick's spokesperson, Bill O'Donnell, as saying "The point is, it has been well-known and widely reported since the 1960s that average wholesale price does not reflect actual prices."[63] According to an article in the *Lexington Herald Leader*, the Kentucky attorney general sued five drug companies, using prices for albuterol as an example: AWP is $21.41, retail price is ca. $17, and cost to pharmacy is $3.75; "a difference of over 570 percent."[64]

24. An article in the September 29, 2003, *Times-Picayune* reported on the reaction of oncologists to proposed legislation that would reduce reimbursement for drugs. The article said that doctors paid between 13 and 34 percent less than AWP and cited U.S. Representative Billy Tauzin as saying, "... the difference between what some doctors paid and what they were reimbursed by the government was vast.

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60 Iglehart, John K., "Medicare and Drug Pricing," Health Policy Report, *New England Journal of Medicine,* April 17, 2003, p. 1590.

61 *Ibid.*, p. 1593.

62 Pear, Robert, "Cancer Drugs Face Funds Cut in a Bush Plan," *The New York Times*, Section A, August 6, 2003, p. 1.

63 Hanners, David, "Drug Price Boost Alleged," *Saint Paul Pioneer Press*, Business, August 28, 2003, p. 1C. Warrick is the generic drug subsidiary of Schering-Plough.

64 Brammer, Jack, "Drug Makers Cheated State, Lawsuit Says," *Lexington Herald Leader*, City and Region, September 16, 2003, p. B1.

Sometimes the discounts are much deeper ..."[65] The article also cited ASCO "estimates [that] Medicare covers about 25 percent of the clinical, administrative and labor costs associated with administering chemotherapy drugs." On October 29, 2003, *Drug Industry Daily* reported that CMS would delay its issuance of a final rule on drug reimbursement for Medicare Part B drugs, because CMS wants "... to give Congress the opportunity to act."[66] Another article on the same subject appeared in the November 5, 2003 issue of *Generic Line*.[67]

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65 Walsh, Bill, "Medicare law provision would trim drug profits," *Times-Picayune*, September 29, 2003, p. 4.

66 "CMS Delaying Final Rule as Congress Debates AWP," *Drug Industry Daily*, October 29, 2003.

67 "AWP Methodology Final Rule Delayed by Medicare Debate," *Generic Line*, Vol. 20, No. 21, November 5, 2003.

EXHIBIT A

INTERNATIONAL

GREGORY K. BELL

Group Vice President

Ph.D. Business Economics,
Harvard Graduate School of Arts and Sciences/
Harvard Graduate School of Business Administration

M.B.A. Harvard Graduate School of Business Administration

B.A. Simon Fraser University

Dr. Bell, group vice president at CRA International, is responsible for business consulting and also the practice leader for pharmaceuticals and intellectual property. In addition, he is a principal member of the firm's Finance and Transfer Pricing practices. As an expert witness, Dr. Bell frequently testifies on damages in intellectual property, finance, and antitrust litigation. Dr. Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets. He has led and consulted to numerous projects concerning game theory and competitive strategy, global launch strategy, product pricing and positioning, capital budgeting and real options, and cost-benefit analyses.

EXPERIENCE

Business

1992–Present *Group Vice President*, CRA International, Boston, MA

- Dr. Bell directs CRA's Pharmaceuticals and Intellectual Property practices.

1987 *Management Consultant*, Alliance Consulting Group, Boston, MA

- Dr. Bell designed a market research program for a consumer electronics client's new product development.

1986 *Associate*, Corporate Finance, Wood Gundy, Vancouver, Canada

- Dr. Bell participated in drafting the prospectus and in marketing the initial public offering of a sportswear manufacturer.

1982–1985 *Chartered Accountant*, Pannell Kerr Forster, Victoria, Canada

- Dr. Bell provided financial accounting, auditing, taxation, and related management consulting services, focusing on special projects involving accounting theory, financial forecasts, and business valuations.
- He also developed a course to prepare the national firm's articling students for the uniform final examination, an examination required to receive the designation of chartered accountant.
- Dr. Bell placed eighth in Canada on the 1983 uniform final examination and was named to national honor roll.

Academic

1991–1992 *Visiting Assistant Professor*, Economics Department, Northeastern University.

- Dr. Bell was responsible for undergraduate courses in industrial organization, managerial economics, and principles of microeconomics.

1991–1992 *Lecturer*, Economics Department, Harvard University.

- Dr. Bell developed the senior-level undergraduate course, "Economics of Business Strategy."

Section Leader, Economics Department, Harvard University.

- Dr. Bell led sections in industrial organization.

1990–1991 *Research Associate*, Economics Department, Harvard University.

- Dr. Bell conducted mergers and acquisitions analysis.

1982 *Research Assistant*, Economics Department, Simon Fraser University.

- Dr. Bell performed capital markets analysis.

PUBLICATIONS

"Global Pricing Strategies for Pharmaceutical Product Launches." With P. Rankin and T. Wilsdon. Chapter 2 of *The Pharmaceutical Pricing Compendium*, pp. 13–23, Urch Publishing Ltd, 2003.

"Cost Implications of Low Molecular Weight Heparins as Prophylaxis Following Total Hip and Knee Replacement." With S. Goldhaber. *Vascular Medicine* (February 2001).

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"Cost-Effectiveness Analysis of Spinal Cord Stimulation in Treatment of Failed Back Surgery Syndrome." With D. Kidd and R. North. *Journal of Pain and Symptom Management* (May 1997).

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"Irreversible Investments and Volatile Exchange Rates: Theory and Evidence." Ph.D. Thesis, Harvard University, 1992.

PRESENTATIONS

"Damages: Lost Profits, Consequential Damages, Damages for Non-Patented Items, Best Practices for the Use of Experts." Panel participant for The Fifth Annual Sedona Conference on Patent Litigation, Sedona, AZ, October 2004.

"Patent Damages: Engineering and Regulatory Work-Arounds." Calculating and Proving Patent Damages, Law Seminars International, Reston, Virginia, June 14, 2004.

"Pricing Strategy and the Product Line." Pricex 2003, Chicago, IL, June 11, 2002.

"Reasonable Royalties for Emerging Technologies." Chaired Panel for The Third Annual Sedona Conference on Patent Litigation, Sedona, AZ, November, 2002.

"Does Price Matter? Pricing, Game Theory, and the Economics of Business Strategy." Pricex 2002, Chicago, IL, April 30, 2002.

"eCommerce and Strategy for the Pharmaceuticals Industry." Chairman for The Canadian National e-Pharma Summit II, Toronto, Canada, June 26–27, 2001.

"Exports and Flexible Production Technologies in Volatile International Markets." 4th Annual Conference on Real Options, Cambridge, UK, July 7–8, 2000.

"The Valuation of Oil Drilling Rights: A Real Options Case Study." 2nd Annual Conference on Real Options, Chicago, IL, June 11–12, 1998.

"Prejudgment Interest." Conference: Charles River Associates' Economists' Perspectives on Antitrust Today—Session: Topics in Calculating Damages, Boston, MA, April 30, 1998.

"Designing Licenses that Maximize Client Profits." American Intellectual Property Law Association Spring Meeting, Minneapolis, MN, April 23, 1998.

"Economics of Therapy." Nonmalignant Pain Management Roundtable, Memphis, TN, January 9, 1997.

"How to Structure Risk-Sharing Contracts to Put Teeth in Disease Management." Congress on Health Outcomes and Accountability, Washington, DC, December 10–13, 1995.

Balancing Low and High Risk Projects." Institute for International Research, Portfolio Planning & Management Conference, Philadelphia, PA, October 23–25, 1995.

"Capitated Pricing for Pharmaceuticals." Medical Marketing Association National Meeting, Monterey, CA, June 1995.

"Evaluating the Cost-Effectiveness of Pharmaceuticals." Anti-Rheumatic Guidelines and International Society for Rheumatic Therapeutics, Scottsdale, AZ, May 1995.

"The Role of Pharmacoeconomics in the Drug Approval Process." Anti-Rheumatic Guidelines and International Society for Rheumatic Therapeutics, Scottsdale, AZ, May 1995.

"Compliance with Section 482." With D. Wright. Institute for International Research, *Practical Approaches to Transfer Pricing* conference, New Orleans, LA, February 22–23, 1995.

"XYZ Corporation: A Case Study in Transfer Pricing." With D. Wright. Institute for International Research, *Practical Approaches to Transfer Pricing* conference, New Orleans, LA, February 22–23, 1995.

"Medtronic's Spinal Cord Stimulation Systems: Reimbursement and Marketing Strategy." Sloan School, Massachusetts Institute of Technology, Cambridge, MA, June 1993.

"Exports and Production Technology under Volatile Exchanges Rates." Stanford University, Stanford, CA, February 1992.

"Capacity and Volatile Exchange Rates: A Study of the Chemical Processing Industry." London Business School, London, United Kingdom, March 1991; University of Michigan, Ann Arbor, MI, March 1991; University of British Columbia, Vancouver, BC, February 1991; Kellogg School of Management, Northwestern University, Evanston, IL, January 1991.

TESTIMONY

Expert report and deposition testimony on behalf of Plaintiff in *LoJack Corporation v. Clare, Inc.* (December 2005, January 2006, March 2006). Commonwealth of Massachusetts Superior Court, Civil Action No. 03-00627.

Expert report and deposition testimony on behalf of Defendant in *PHT Corporation v. Invivodata, Inc.* (November, December 2005). U.S. District Court of Delaware, C.V. No. 04-60 GMS.

Expert report and deposition testimony on behalf of Defendant in *PHT Corporation v. CRF, Incorporated* (November, December 2005). U.S. District Court of Delaware, C.V. No. 04-61 GMS.

Expert reports on behalf of GlaxoSmithKline Inc. in *Her Majesty The Queen v. GlaxoSmithKline* (October 2005, January 2006). Tax Court of Canada, Court File No.98-712(IT)G.

Expert report and deposition testimony on behalf of Plaintiffs in *IVPCare, Inc.v. Harvard Pilgrim Health Care, Inc.* (October, November 2005). Superior Court Department of the Trial Court, Commonwealth of Massachusetts, Civil Action No. 03-5058-BLS.

Expert reports on behalf of Plaintiffs in *Pharmacia & Upjohn Company, LLC v. Sicor Inc., et al.* (September 2005, February 2006). U.S. District Court of Delaware, C.A. No. 04-833 (KAJ).

Expert reports and deposition testimony on behalf of Wyeth, Inc. in *Applera Corporation et al.* v. *Wyeth, Inc.* (August, September, October 2005). Circuit Court for Montgomery County, Maryland, Civil Action No. 242761.

Expert reports and deposition testimony on behalf of Defendant Medco Health Solutions, Inc., et al. in *U.S. Government* v. *Merck-Medco et al.* (August, September, October, November 2005). U.S. District Court, Eastern District of Pennsylvania, No. 00-CV-737.

Expert reports and deposition testimony on behalf of Defendant FMC Corporation in *Microcrystalline Cellulose Antitrust Litigation* (April, May, June 2005). U.S. District Court, Eastern District of Pennsylvania, Master File No. 01-CV-111 (O'Neill, J.) MDL No. 1402.

Expert report on behalf of Defendants in *Robert J. Swanston* v. *TAP Pharmaceutical Products, Inc., et al.* (February 2005). Superior Court of the State of Arizona in and for the County of Maricopa, Cause No. CV2002-004988.

Expert reports on behalf of Joint Services International, B.V. in *Joint Services International, B.V.* v. *O'Neill, Inc.* (January, April 2005). London Court of International Arbitration, LCIA Arbitration No. 3513.

Expert report and deposition testimony on behalf of Defendants in *RoseMarie Ryan-House, et al.* v. *GlaxoSmithKline, et al.* (December 2004). United States District Court, Eastern Division of Virginia, Civil Action No. 2:02cv442.

Expert tutorial and testimony on behalf of Fast Track Defendants in *Pharmaceutical Industry Average Wholesale Price Litigation* (December 2004). United States District Court, District of Massachusetts, Civil Action No. 01-CV-12257 PBS.

Expert report and deposition testimony on behalf of Yangtze Optical Fibre and Cable Company Ltd. in *Yangtze Optical Fibre and Cable Company LTD.* v. *Lucent Technologies Inc.* (November 2004, March 2005). United States District Court, District of Massachusetts, Civil Action No. 03CV11413EFH.

Expert report and deposition testimony on behalf of Defendants in *Medtronic Vascular, Inc.* v. *Boston Scientific Corporation, et al.*, (July, August 2004). United States District Court, District of Delaware, Civil Action No. 98-478 SLR.

Expert report and deposition testimony on behalf of Mylan Laboratories, Inc., et al., in *Lorazepam & Clorazepate Antitrust Litigation* (May, June 2004). United States District Court, District of Columbia, MDL No. 1290 (TFH).

Affidavit on behalf of Novopharm Limited in *Pfizer Canada et al.* v. *The Minister of Health and Novopharm Limited* (May 2004). Federal Court, Court File No. T-2448-03.

Expert report and deposition testimony on behalf of Bayer AG and Bayer Corporation in *Ciprofloxacin Hydrochloride Antitrust Litigation* (April, May 2004). United States District Court, Eastern District of New York, Master File No. 1:00-MD-1383.

Affidavit and testimony on behalf of Novopharm Limited in *Merck & Co et al.* v. *The Minister of Health and Novopharm Limited* (April, August 2004). Federal Court, Court File No. T-1627-03.

Expert report and deposition testimony on behalf of SRU BioSystems et al. in *Corning Incorporated et al.* v. *SRU BioSystems et al.* (April, May 2004). United States District Court, District of Delaware, Civil Action No. 03-633-JJF.

Expert reports and testimony on behalf of Respondent in *Roche Diagnostics GmbH* v. *SmithKline Beecham (Cork) Ltd* (January, April, July 2004). ZCC Arbitration No. 362.

Expert report and testimony on behalf of Hans-Werner Hector in *Hans-Werner Hector* v. *The Bank of America Corporation et al.* (January, April 2004). American Arbitration Association.

Expert report on behalf of Enzo Biochem, Inc. in *Enzo Biochem, Inc.* v. *Gen-Probe, Inc. et al.* (December 2003). United States District Court, Southern District of New York, Civil Action No. 99-4548 (AKH).

Expert report on behalf of Defendants in *Truitt Enterprises et al.* v. *Union Security Life Insurance Company et al.* (November 2003). United States District Court, District of Maryland (Northern Division), Civil Action No. 03-1422.

Expert report and deposition testimony on behalf of Plaintiffs in *DataSafe, Inc. et al.* v. *Federal Express Corporation et al.* (August 2003, January 2004). Commonwealth of Massachusetts, Superior Court Department, Civil Action No. 01-2590.

Expert report on behalf of SmithKline Beecham Animal Health Inc. in *SmithKline Beecham Animal Health Inc.* v. *Her Majesty The Queen* (July 2003). The Court of Queen's Bench, File No. 95-1077 (IT) G.

Expert report on behalf of Bayer Corporation in *Cipro Cases I & II* (June 2003). Superior Court of the State of California, County of San Diego, JCCP. Proceeding Nos.: 4154 & 4220.

Expert reports and deposition testimony on behalf of Defendants in *Johnson Matthey Inc.* v. *Research Corporation, et al.* (March, April 2003). United States District Court, Southern District of New York, Case No. 01-CV-8115 (MBM).

Expert report and deposition testimony on behalf of Bayer AG in *Anne Cunningham, et al.* v. *Bayer AG, et al.* (March, April 2003). Supreme Court of the State of New York, County of New York, Index No. 603820-00.

Expert reports and deposition testimony on behalf of Plaintiff in *Star Scientific* v. *R.J. Reynolds Tobacco Company* (January, March 2003, October 2004). United States District Court for the District of Maryland, Southern Division, Case No. AW 01-CV-1504 and AW 02-CV-2504.

Expert report and deposition testimony on behalf of Defendants in *Tyco Adhesives LP* v. *Olympian Tape Sales, Inc. et al.* (August, October 2002). United States District Court, District of Massachusetts, Civil Action No. 00-11965-NG.

Expert report on behalf of Defendant in *Cook Incorporated* v. *Boston Scientific Corporation* (August 2002). United States District Court for the Northern District of Illinois, Eastern Division, Civil Action No. 01-CV-9479.

Deposition testimony and trial testimony on behalf of Defendants in *Engelhard Corporation* v. *Research Corporation, et al.* (July, October 2002). Supreme Court of the State of New York, County of New York, Index No. 601847/98.

Expert report and testimony on behalf of Plaintiffs in *Biovail Laboratories Incorporated* v. *Mylan Pharmaceuticals, Inc.* (July 2002, January 2003). American Arbitration Association, Case No. 50T13329601.

Expert reports and deposition testimony on behalf of Plaintiffs in *Novartis Consumer Health, Inc.* v. *Elan Transdermal Technologies et al.* (June, July, August 2002). United States District Court Southern District of Florida, Miami Division, Civil Action No. 01-1120-CIV-MOORE.

Expert report on behalf of Defendants in *Frederick F. Buechel, M.D. and Michael J. Pappas, Ph.D.* v. *John N. Bain, John G. Gilfillan, III et. al.* (March 2002). Supreme Court of the State of New York County of New York, No. 106963/95.

Expert reports and deposition testimony on behalf of Defendants in *National Rural Electric Cooperative Association et al.* v. *Breen Capital Services Corporation et al.* (February 2002, October 2004). United States District Court of New Jersey, Civil Action No. 2:00cv00722.

Expert report on behalf of Aesculap in *Aesculap AG & Co. et al.* v. *Walter Lorenz Surgical, Inc.* (November 2001). United States District Court for Northern District of California, No. C00-02394-MJJ.

Certification on behalf of Defendants in *Louise Garretson et al.* v. *CSFBTLC Trust II et al.* (October 2001). United States Superior Court for the District of New Jersey, No. HUD-L-3117-00.

Expert report and trial testimony on behalf of C.R. Bard, Inc., in *N.M.T. Medical, Inc.* v. *C.R. Bard, Inc.* (April 2001). American Arbitration Association, AAA Case No. 11 199 00973 00.

Expert report and trial testimony on behalf of Boston Scientific Corp., et al. in *Boston Scientific Corp. et al.* v. *Medtronic AVE, Inc.* (March and April 2001). American Arbitration Association, AAA File No. 50 T 133 00307 00.

Expert report and deposition testimony on behalf of Defendants in *DuPont Pharmaceuticals, et al.* v. *Molecular Biosystems, Inc., et al.* (January and February 2001). United States District Court for the District of Delaware, Civ. No. 99-273 (JJF).

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Expert report on behalf of Artegraft, Inc., in *Ethicon Inc. and Johnson & Johnson Consumer Products Inc.* v. *Artegraft, Inc.* (September 1998). American Arbitration Association, File 18-199-00136-96.

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Expert reports and deposition testimony on behalf of Glaxo Wellcome in *Emory University* v. *Glaxo Wellcome* (February 1998, August 1998, September 1998). United States District Court for the Northern District of Georgia, 96-CV-1754.

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Expert reports on behalf of American Home Products in *Johnson & Johnson* v. *American Home Products* (June 1996). United States District Court for the Eastern District of Pennsylvania, 94-CV-1388.

Testimony on behalf of Novo Nordisk in *Genentech, Inc.* v. *Novo Nordisk A/S et al.* (May 1996). United States District Court for the Southern District of New York, 96-CV-1755.

CONSULTING PROJECTS

Adult Nutritionals

- Evaluate opportunity to purchase pumps and plastics business for enteral feeding.
- Assess value of a patient / consumer regarding awareness / trial / usage. Market research involving patients.
- Assess value of hospital contracts for feeding systems in Canada. Market research involving patients and hospitals.

Antibiotics

- Pricing and managed care strategy to support launch of quinolone. Market research with managed care and physicians.
- Evaluation of European reimbursement environment for launch of quinolone.
- Managed care strategy for quinolone. Market research with managed care.
- Pricing and managed care strategy to support launch of ketolide. Market research with managed care and physicians.

Blood Products

- Cost-effectiveness study for anti-clotting product.
- Strategy for anti-anemia product as it faces competing entry. Market research with managed care, physicians and hospitals. Address new Medicare policies regarding ASP and CAP.
- Pricing and managed care strategy for anti-clotting product facing competing entry. Market research with managed care and physicians.
- Reimbursement issues for clotting factor.

Cardiovascular Products

- Managed care contracting strategy for statins. Market research with physicians.
- Capitated pricing strategy for statins.
- Pricing and managed care strategy to support global launch of a new class of cardiovascular products for the treatment of hypertension and heart failure. Markets include US, Canada, Europe. Market research with managed care and physicians.

- Managed care strategy for anti-platelet product.

CNS Products

- Managed care strategy for anti-arthritic.
- Pricing and managed care strategy to support launch of prescription pain product. Market research with managed care, physicians and patients.
- Managed care strategy to support dissolving formulation of anti-psychotic.
- Strategy review for Alzheimer's product.
- Managed care strategy for insomnia product facing competitive entry. Market research with managed care.
- Managed care strategy and salesforce training to support launch of depot formulation of anti-psychotic. Market research with managed care.
- Managed care strategy to protect opioid analgesic business as product goes generic. Market research with managed care and physicians.
- Managed care strategy to support franchise products for the prevention and treatment of migraines.
- Managed care strategy to support anti-psychotic franchise confronting competing entry, generic penetration, and preparation for launch of second-generation product. Market research with managed care.
- Pricing and managed care strategy to support the launch of a long-acting opioid. Market research with managed care, physicians and patients.
- Opportunity assessment for new patch product for Alzheimer's disease. Markets include US and Europe. Market research with managed care, physicians and care-givers.

Endocrinology

- Managed care strategy to support the launch of extended-release and combination diabetes products.
- Pricing and managed care strategy to support launch of menopause product. Market research with managed care and physicians.
- Pricing and managed care strategy to support launch of an orphan drug product for Gaucher's disease. Market research with managed care, physicians and patients.

Gastro-Intestinal Products

- Cost-effectiveness study of GI impact of NSAIDs.
- Capitated pricing strategy for H2 antagonists.
- Managed care strategy and salesforce training to support the launch of PPI. Market research with managed care and physicians.
- Capitated pricing strategy for PPI.
- Impact of launch of competing PPI. Market research with managed care and physicians.
- Impact of PPI going generic.

Infant Formula

- Value of government (WIC) contracts in the infant formula business. Study covered all aspects of recommendation and consumption behavior and all aspects of manufacturing and distribution, including shelf facings at drug stores, mass merchandisers and super-markets. Market research focused on purchasing and consumption behavior.
- Advise on bid pricing strategy for government contracts.
- Advise on likely exit strategy of competitor.
- Optimal size for ethical salesforce, calling on hospitals and pediatricians.
- Design program for private-sector leadership to combat low-birthweight.
- Assess opportunity for new manufacturing facility and packaging options.
- Advise on likely entry strategy of potential competitor.
- Pricing strategy across product line. Market research with consumers.

Oncology

- Strategy for second-generation oncolytic as predecessor product goes generic. Market research with physicians and hospitals.
- Strategy for oncolytic as it goes generic. Market research with physicians and hospitals.
- Pricing and managed care strategy to support the launch of a second-generation oncolytic. Market research with physicians and hospitals.

- Diagnostic strategy for breast cancer. Market research with physicians.
- Contracting strategy alternatives to support the launch of an oncolytic.

Other

- Pricing and managed care strategy to support the launch of a prescription facial hair removal product.
- Managed care strategy to support incontinence product. Market research with managed care, physicians and patients.
- Managed care strategy to support the launch of a product for premature ejaculation. Market research with managed care, physicians and patients.
- Distribution strategy for a specialty pharmacy asthma product.
- Advise on global pricing for growth hormone anticipating competitive entry.

General Strategy

- Evolution of managed care and its impact on the pharmaceutical industry.
- Strategy for the retail pharmacy.
- Innovations in managed care contracting.
- Assessment of B2B e-commerce strategy for the pharmaceutical industry.
- Contracting for all manufacturer products with major US PBM.
- Forced conversion to OTC status.
- Innovation in the pharmaceutical industry: Opportunities for Europe.
- Tender pricing strategy and implementation. Pilot test covers Mexico, Brazil, Taiwan, Australia, UAE.
- Strategy for Medicare Part D.
- Reference pricing and the impact on innovation the pharmaceutical industry in Europe

HONORS AND AWARDS

- Dean's Doctoral Fellow, Harvard Graduate School of Arts and Sciences/ Harvard Graduate School of Business Administration.
- George Baker Scholar, John Thayer Scholar, Frank Knox Memorial Fellow, McKenzie King Traveling Scholar, Harvard Graduate School of Business Administration.
- Governor General's Gold Medal, Gordon Shrum Scholar, Simon Fraser University.

Exhibit B: Materials Relied Upon

Outside Material

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Baker, Thomas, "Specialty Therapies Lose Special Status: Survey Results Say Managed Care is Revamping the Way it Handles Biologics," *Pharmaceutical Executive*, September 2004, http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=123007.

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